UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION

THIS DOCUMENT RELATES TO:
The County of Summit, Ohio, et al. v. Purdue Pharma L.P., et al.
Case No. 18-op-45090

The County of Cuyahoga, Ohio, et al. v. Purdue Pharma L.P., et al.
Case No. 17-op-45004

MDL No. 2804

Case No. 1:17-md-2804

Judge Dan Aaron Polster

THE NON-RICO SMALL DISTRIBUTORS' MEMORANDUM IN SUPPORT OF THEIR MOTION FOR PARTIAL SUMMARY JUDGMENT ON PLAINTIFFS' "FAILURE TO REPORT" AND "FRAUD ON THE DEA" CLAIMS

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INTRODUCTION

The non-RICO Small Distributors[1] (Anda, H. D. Smith,[2] Henry Schein, and Prescription Supply) are entitled to partial summary judgment on all claims and allegations that the Small Distributors failed to comply with obligations imposed by the federal Controlled Substances Act and its implementing regulations ("CSA"); specifically, that they are liable to Plaintiffs because they allegedly committed a "fraud on the DEA," and that they are liable to the Plaintiffs for failing to report allegedly "suspicious orders" to the DEA, because:

(i) Ohio law does not recognize such "fraud on the agency" claims;

(ii) the Controlled Substances Act does not provide a private right of action or private remedy for such claims, nor do Article III constitutional constraints allow federal courts to consider such claims; and

(iii) implied conflict preemption principles under *Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), bar such state law claims.

This motion is authorized by Fed. R. Civ. P. 56(a), which allows summary judgment to proceed against "the ***part*** of each claim . . . on which summary judgment is sought." (emphasis added). *See, e.g.*, *In re Gadolinium-Based Contrast Agents Prods. Liab. Litig.*, 2013 WL

[1] More specifically, the term "Small Distributors," as used in this motion, includes Defendants Anda, Inc.; H. D. Smith, LLC (as well as non-operating entities H. D. Smith Holding, LLC and H. D. Smith Holding Company); Henry Schein, Inc. (as well as Henry Schein Medical Systems, Inc. – which does not sell opioids); and Prescription Supply Inc. Plaintiffs do not assert either their fraud claim (Count VIII) or their state and federal RICO claims (Counts I–IV) against the Small Distributors. The Small Distributors have together also filed a summary-judgment motion on grounds of *de minimis* supply concurrently herewith.

[2] On October 2, 2018, H. D. Smith Holdings, LLC and H. D. Smith Holding Company (the "Holding Companies") moved to dismiss the Second Amended Corrected Complaint in *The County of Cuyahoga, Ohio, et al. v. Purdue Pharma L.P., et al.*, Case No. 1:17-op-45004 (N.D. Ohio) based on lack of personal jurisdiction, pursuant to Fed. R. Civ. P. 12(b)(2). ECF No. 1015. Plaintiffs have not filed an opposition, nor has the Court issued a ruling. By joining in any motion in the above-referenced matter, the Holding Companies are in no way waiving their previously asserted defense that the Court lacks personal jurisdiction over the Holding Companies and must dismiss them from this case, pursuant to Fed. R. Civ. P. 12(b)(2).

587655, at *14 (N.D. Ohio Feb. 13, 2013) (Polster, J.) (granting partial summary judgment because *Buckman* "applies to every legal theory—whether that theory is part of a claim or remedy—that requires proof of fraud on or misrepresentation to, the FDA.").

The Small Distributors are named as defendants only in the Plaintiffs' Fifth Claim for Relief, Statutory Public Nuisance; Sixth Claim for Relief, Common Law Absolute Public Nuisance; Seventh Claim for Relief, Negligence; Ninth Claim for Relief, Injury through Criminal Acts; Tenth Claim for Relief, Unjust Enrichment; and Eleventh Claim for Relief, Civil Conspiracy. The Small Distributors do not move for summary judgment against the entirety of any separate claim for relief with this motion. Instead, they move for partial summary judgment against those parts of each claim that alleges liability for failure to report to the DEA or fraud on the DEA, as those allegations appear in each of the separate Claims asserted against the Small Distributors.

Specifically, such claims are common allegations made or incorporated by reference in each of these claims. *See, e.g.*, Cuyahoga County's Third Amended Complaint ("TAC") ¶ 1104 ("Defendants[']conduct was negligence *per se* in that Defendants violated federal law, including, but not limited to, 21 U.S.C. §§ 823 and 827(d)(1); 21 C.F.R. §§ 1301.74, 1304.21, 1304.22, and 1304.33(e)[.]"). *See also id*. ¶ 1052 ("In the sale and distribution of opioids in Ohio and Plaintiff's Community, Defendants violated federal law, including but not limited to, 21 U.S.C.A. § 823 and 21 C.F.R. § 1301.74[.]"); *id.* ¶ 548 ("Defendants refused to identify, investigate and report suspicious orders to the DEA[.]"); *id.* ¶ 810 ("Defendants' agreement to restrict reporting provided an added layer of insulation from DEA scrutiny[.]"); *id.* ¶ 826 ("Defendants acted in concert together to . . . ensure that suspicious orders would not be reported[.]").

Indeed, the "fraud on the DEA" theme is prevalent throughout Summit and Cuyahoga's respective TACs and is addressed at length in interrogatory responses[3] in which Plaintiffs contend that "each of the Distributor Defendants" provided false information to or otherwise committed fraud on the DEA by failing to report suspicious orders or otherwise failing to meet requirements of the CSA.[4] These are exactly the kinds of claims that should be disposed of by partial summary judgment, as set forth below.

ARGUMENT

I. OHIO LAW REJECTS CLAIMS BASED ON "FRAUD ON A FEDERAL AGENCY" OR "FAILURE TO REPORT."

Plaintiffs allege that, "First, under the common law, the Defendants had a duty [which they breached by] failing to report orders that they knew or should have realized were likely being diverted for illicit uses." TAC ¶ 486. The Plaintiffs also allege that the "Defendants breached their duty ***to Plaintiff*** by, *inter alia*, . . . [c]hoosing not to report suspicious orders[.]" TAC ¶ 1089 (emphasis added). But Ohio common-law does not recognize any such duties.[5]

Less than four months before the Supreme Court's decision in *Buckman Company v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), the Sixth Circuit addressed Ohio "fraud on the

[3] Although Cuyahoga's TAC and discovery responses are referenced herein for illustration purposes, the same themes and issues are reflected in allegations and responses of Summit County as well.

[4] Ex. A (Pl Cuyahoga County's Supp. Resps. and Objections to Distributor Def's Interrogs., March 4, 2019, Resp. to Interrogatory No. 24) at 42-54.

[5] This Court's prior Order accepting in part the Magistrate's Report and Recommendation did not reach these specific arguments and the authorities cited herein. "The R&R expressly did not reach whether any Defendant owed a duty to Plaintiffs under the [CSA] or [its] regulations. It also did not address whether the [CSA] or [its] regulations create a common law duty under a negligence *per se* theory. . . . [The Distributors] assert[ed] that the R&R identified no Ohio case recognizing a common-law duty to *report . . . suspicious orders of controlled substances* and [that] no authority suggests that such a duty runs to the cities or counties. The duty that Plaintiffs allege is not so narrow." *In re Nat'l Prescription Opiate Litig.*, 2018 WL 6628898, at *18-19 (N.D. Ohio Dec. 19, 2018) (internal quotation marks and citations omitted, original emphasis).

FDA" claims in *Kemp v. Medtronic, Inc.*, 231 F.3d 216 (6th Cir. 2000). Appealing from summary judgment against their claims, the Kemps argued that Medtronic committed a "Fraud on the FDA." *Id*. at 233. The Sixth Circuit held such claims both preempted and barred as an attempt to state a prohibited private cause of action under the FFDCA. But the court also addressed the question whether Ohio law would recognize such a claim in the first place.

Medtronic "argu[ed] that Ohio law does not recognize a common-law cause of action for alleged fraud on a federal agency." *Id*. The Sixth Circuit agreed that "claims alleging fraud on federal agencies have never come within the 'historic police powers of the States[.]'" *Id*. at 235.[6] *See also id*. at 238 (Moore, J., concurring) ("Kemp fails to point to any Ohio law upholding the viability of a 'fraud against a federal agency' claim[.]"). Further, Ohio's federal district courts hold that while a medical device manufacturer has a federal duty to report adverse events to the FDA, there is no Ohio common-law duty to do so. *E.g.*, *Warstler v. Medtronic, Inc.*, 238 F. Supp. 3d 978, 989 (N.D. Ohio 2017); *Aaron v. Medtronic, Inc.*, 209 F. Supp. 3d 994, 1005 (S.D. Ohio 2016).[7]

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[6] The Supreme Court, affirming *Kemp*'s principles, later agreed. *See Buckman*, 531 U.S. at 347 ("Policing fraud against federal agencies is hardly a field which the States have traditionally occupied[.]" (internal quotation marks and citation omitted)).

[7] Such holdings are common from the courts of many states. *E.g.*, *Conklin v. Medtronic, Inc.*, 431 P.3d 571, 578 (Ariz. 2018) ("only federal law, not state law, imposes a duty on Medtronic to submit adverse event reports to the FDA[.]"); *McNeil-Williams v. DePuy Orthopaedics, Inc.*, ___ F. Supp. 3d ___, 2019 WL 2339258, at *5 (E.D. N.C. May 29, 2019) ("North Carolina law . . . does not recognize an independent state law duty to make adverse event reports to the FDA."); *White v. Medtronic, Inc.*, 2019 WL 1339613, at *6 (E.D. Mich. Feb. 20, 2019) ("the federal requirement that manufacturers report adverse events to the FDA has no state law analog[.]"); *Romer v. Corin Group, PLC*, 2018 WL 4281470, at *7 (M.D. Fla. Sept. 7, 2018) ("Florida law does not provide a duty to file [adverse event] reports with the FDA [.]"); *Kubicki on behalf of Kubicki v. Medtronic, Inc.*, 293 F. Supp. 3d 129, 183 (D. D.C. 2018) (noting "the undisputed fact that there is no D.C. common law claim that imposes liability for a manufacturer's failure to report to the FDA adverse incidents concerning an approved medical device."); *Norman v. Bayer Corp.*, 2016 WL 4007547, at * 4 (D. Conn. July 26, 2016) ("There is no general or background duty under Connecticut law to report risks *to a regulatory body*." (original emphasis)).

It necessarily follows, therefore, that Ohio does not recognize a common-law cause of action for failure to report more "suspicious orders" to the DEA, much less an action for failure to report a sufficient number of suspicious orders. And separately from the constitutional prohibitions barring federal courts from implying private rights of action and private remedies under federal statutes where Congress itself has not expressly done so, discussed below, federal courts may not conjure up such novel state-law causes of action. *See, e.g., Combs v. Int'l Ins. Co.*, 354 F.3d 568, 577 (6th Cir. 2004).

II. THE CSA DOES NOT PROVIDE A PRIVATE RIGHT OF ACTION OR A PRIVATE REMEDY, AND ARTICLE III DOES NOT PERMIT FEDERAL COURTS TO ENTERTAIN SUCH CLAIMS PURSUED UNDER STATE LAW PLEADING LABELS.

The Plaintiffs allege that, "Defendants[']conduct was negligence *per se* in that Defendants violated federal law, including, but not limited to, 21 U.S.C. §§ 823 and 827(d)(1); 21 C.F.R. §§ 1301.74, 1304.21, 1304.22, and 1304.33(e)[.]" TAC ¶ 1104. All courts agree, however, that "[t]he CSA does not provide a private cause of action. Instead, it delegates the power of enforcement of federal drug policy to the federal government." *McKesson Corp. v. Hembree*, 2018 WL 340042, at *5 (N.D. Okla. Jan. 9, 2018) (collecting authorities); *see also Safe Streets All. v. Alternative Holistic Healing, LLC*, 2016 WL 223815, at *3 (D. Colo. Jan. 19, 2016) (collecting authorities), *aff'd sub nom.*, *Safe Streets All. v. Hickenlooper*, 859 F.3d 865 (10th Cir. 2017); 28 C.F.R. § 0.55(c) (The Assistant Attorney General, Criminal Division, is responsible for "[a]ll criminal and civil litigation under the Controlled Substances Act[.]").

If a federal statute does not expressly provide both a private right of action and a private remedy, then constitutional separation-of-powers principles bar federal courts from implying them. "[W]hen a party seeks to assert an implied cause of action under a federal statute, separation-of-powers are or should be central to the analysis." *Ziglar v. Abassi*, 137 S. Ct. 1843,

1857 (2017). "[C]ourts must refrain from creating [a private] remedy in order to respect the role of Congress in determining the nature and extent of federal-court jurisdiction under Article III." *Id*. at 1858. *See also Stoneridge Inv. Partners, LLC v. Sci.-Atlanta*, 552 U.S. 148, 164-65 (2008).

"The significance of the necessary assumption that there is no federal private cause of action thus cannot be overstated." *Merrell Dow Pharms. Inc. v. Thompson*, 478 U.S. 804, 812 (1986). "[I]t would flout congressional intent to provide a private federal remedy for the violation of the federal statute . . . . and [to] provide remedies for violations of that federal statute solely because the violation of the federal statute is said to be a 'rebuttable presumption' or a 'proximate cause' under state law, rather than a federal action under federal law." *Id*. (footnotes omitted). *See also id*. at n.10.

Thus, plaintiffs may not slip in a forbidden private cause of action through the back door of a state-law negligence per se claim—as the Plaintiffs attempt to do here. *E.g.*, *Myers v. U.S.*, 17 F.3d 890, 901 (6th Cir. 1994) ("[P]laintiffs' claim must fail because, were we to permit them to proceed on the basis of negligence per se, we would, in effect, be permitting a private cause of action under the Act. This we refuse to do."). *See also Towne Auto Sales, LLC v. Tobsal Corp.*, 2017 WL 5467012, at *2 (N.D. Ohio Nov. 14, 2017) (dismissing negligence per se claim where both the federal Patriot Act and Bank Secrecy Act required banks "to report suspicious activity indicative of criminal activities to the government," but, because neither Act created a private cause of action, the court "perceive[d] no sound reason to recognize a duty of care that is predicated upon the statute's monitoring requirements." (internal quotation marks and citations omitted)); *Sheldon v. Kettering Health Network*, 40 N.E.3d 661, 674 (Ohio App. 2015).

Nor may the Plaintiffs point to other Ohio common-law theories, administrative rules, or statutes to suggest that Ohio state law—as distinct from federal law—might provide private

remedies for violations of the CSA. For instance, in the Plaintiffs' Fifth Claim for Relief, alleging Statutory Public Nuisance, and Sixth Claim for Relief, alleging Common Law Absolute Public Nuisance, the Plaintiffs rely on Ohio Rev. Code § 4729.35, which provides that "[t]he violation by a . . . person of any laws . . . of the United States of America . . . controlling the distribution of a drug of abuse . . . is hereby declared to be inimical, harmful, and adverse to the public welfare of the citizens of Ohio and to constitute a public nuisance." TAC ¶¶ 1021, 1051. But States lack constitutional authority to provide private remedies for violations of federal statutes where Congress itself has not. "[T]he authority to fashion private remedies to enforce federal law belongs to Congress alone." *Halliburton Co. v. Erica P. John Fund, Inc.*, 573 U.S. 258, 284-85 (2014) (citation omitted). *See also Culbreath v. Golding Enters., L.L.C.*, 872 N.E.2d 284, 287-89 (Ohio 2007).

III. PLAINTIFFS' CLAIMS ARE IMPLIEDLY PREEMPTED UNDER *BUCKMAN*.

A. *Buckman* made clear that claims like those made here are impliedly preempted under ordinary conflicts principles.

In *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), the Supreme Court affirmed *Kemp*'s principles and held that where, as here, federal agencies are amply endowed with the authority to detect, police against, and prosecute suspected frauds against them, federal law impliedly preempts state law claims which rely on an alleged lack of candor or fraud in the federal regulatory process. In *Buckman*, "Plaintiffs [claimed that] petitioner made fraudulent representations to the [FDA] in the course of obtaining approval to market" certain medical device components and "that such representations were at least a 'but for' cause of injuries that plaintiffs sustained from the implantation of these devices." *Id*. at 343. However, the Supreme Court held "that such claims" of fraud on the FDA "are preempted by the" federal statutes governing the registrations and regulation of medical devices and their manufacturers. *Id.*

Moreover, "[p]olicing fraud against federal agencies is hardly a field which the States have traditionally occupied, such as to warrant a presumption against finding federal pre-emption of a state-law cause of action. To the contrary, the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law." *Id*. at 347 (internal quotation marks and citations omitted).

"Given this analytical framework . . . the plaintiffs' state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, federal law." *Id*. at 348 (footnote omitted). "The conflict stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and that this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives. The balance sought by the Administration can be skewed by allowing fraud-on-the-FDA claims under state tort law." *Id.* "This flexibility is a critical component of the statutory and regulatory framework under which the FDA pursues difficult (and often competing) objectives." *Id*. at 349.

The Court held that allowing "fraud on the agency" claims would also burden the agency and those it regulates in two more important ways. "State-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives. As a practical matter, complying with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes will dramatically increase the burdens facing potential applicants—burdens not contemplated by Congress in enacting the [relevant statutes]." *Id*. at 350. "Conversely, fraud-on-the-FDA claims would also cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court. Applicants would then have an

incentive to submit a deluge of information that the Administration neither wants nor needs, resulting in additional burdens on the FDA's evaluation of an application." *Id*. at 351.

The Court further explained that if "plaintiffs [were] to maintain their fraud-on-the-agency claims here, they would not be relying on traditional state law which had predated the federal enactments in questions [because] these federal enactments [are] a critical element in their case. [Therefore,] we think this sort of litigation would exert an extraneous pull on the scheme established by Congress, and it is therefore pre-empted by that scheme." *Id*. at 352-53.

Importantly, "[l]ower courts have applied *Buckman*'s reasoning to other federal statutory schemes." *Kobar ex rel. Kobar v. Novartis Corp.*, 378 F. Supp. 2d 1166, 1171 (D. Ariz. 2005) (collecting authorities). "Indeed, in every case where a court has analyzed whether a federal regulatory scheme preempts state law claims that require a plaintiff to prove as an essential element fraud on the federal agency responsible for administering the federal scheme, the court has found preemption of the state law claim." *Id*. at 1174.[8]

B. The Sixth Circuit—And This Court—Have Faithfully Applied *Buckman*'s Teachings.

In *Garcia v. Wyeth-Ayerst Laboratories*, 385 F.3d 961 (6th Cir. 2004), the Sixth Circuit considered a Michigan statute that "provided a general immunity for drug manufacturers with a specific exception for circumstances involving, *inter alia*, fraud on the FDA rather than a

[8] *See also, e.g.*, *Sikkelee v. Precision Airmotive Corp.*, 907 F.3d 701, 716 (3d Cir. 2018) (where plaintiff alleged that aircraft engine manufacturer was negligent because it violated an FAA regulation requiring it to report any failure, malfunction or defect, summary judgment on plaintiff's "failure-to-warn-the-FAA claim" affirmed (citing, *inter alia*, *Buckman*)); *Offshore Serv. Vessels, L.L.C. v. Surf Subsea, Inc.*, 2012 WL 5183557, at *3 (E.D. La. Oct. 7, 2012) ("Plaintiffs' claims of 'fraud-on-the-Coast Guard' impermissibly conflict with federal vessel documentation and coastwise trade laws such that they are preempted in accordance with . . . *Buckman*[.]"); *Nathan Kimmel, Inc. v. DowElanco*, 275 F.3d 1199 (9th Cir. 2002) (plaintiff's claim that a pesticide registrant obtained anticompetitive label restrictions by intentionally submitting false and misleading statements to the EPA preempted under *Buckman*).

specific cause of action for fraud on the FDA." *Id*. at 965-66 (footnote omitted). However, the court held, "[a]s the district court properly found, '*Buckman* teaches that state tort remedies requiring proof of fraud committed against the FDA are foreclosed since federal law preempts such claims.'" *Id*. at 966 (citation omitted).

The court affirmed the district court's preemption decision because "it will merely place responsibility for prosecuting bribery or fraud on the FDA in the hands of the Federal Government rather than state courts." *Id*. at 967. *See also Marsh v. Genetech, Inc.*, 693 F.3d 546, 553 (6th Cir. 2012) ("Marsh's suit would require a court to rule on the adequacy of Genentech's post-marketing disclosures to the FDA, which is the kind of 'inter-branch meddling' that concerned the Court in *Buckman*." (brackets omitted, citing *Garcia*, 385 F.3d at 966)).

The Sixth Circuit in *Marsh* further cautioned that "[h]aving a court determine whether any non-disclosed information may reasonably affect [the FDA's decisions] would both usurp the agency's role and go beyond the court's institutional expertise." *Id*. at 553-54 (citations, internal quotation marks, and footnote omitted). In conclusion, the court held that "Marsh's 'claim' . . . is premised on violation of federal law, implicates the relationship between a federal agency and the entity it regulates, and asks the court to assume a role usually held by the FDA—and is thus preempted." *Id*. at 555. *See also In re: Aredia & Zometa Prods. Liab. Litig.*, 352 Fed. App'x 994, 995 (6th Cir. 2009).

In *In re Gadolinium-Based Contrast Agents Products Liability Litigation*, 2013 WL 587655 (N.D. Ohio Feb. 13, 2013) (Polster, J.), this Court addressed Ohio's product-liability punitive damages statute providing "that a manufacturer of an FDA-approved drug is not liable for punitive damages unless the manufacturer fraudulently withheld from the FDA material and

relevant information or the manufacturer misrepresented such information to the FDA." *Id*. at * 13 (citing O.R.C. § 2307.80(C)(1)(a)). After surveying Sixth Circuit precedent, this Court held that this Ohio statute was preempted because "a punitive-damages claim for an FDA-approved drug is allowed under Ohio law *only if* the FDA has made a finding of either fraud or misrepresentation. There is no such finding here." *Id*. at * 14 (original emphasis). "The point is clear; the *Garcia* rule applies to every legal theory—whether the theory is ***part*** of a claim or remedy—that requires proof of fraud on, or misrepresentation to, the FDA." *Id*. (emphasis added).

Thus, this Court's own ruling on *Buckman* preemption supplies the rule of decision here, and partial summary judgment is therefore required on any "part of a claim . . . that requires proof of fraud on, or misrepresentation to, the [DEA]." *Id.* Nor may the Plaintiffs' conspiracy claim escape this rule. *E.g.*, *Morgan v. Brush Wellman, Inc.*, 165 F. Supp. 2d 704, 722 (E.D. Tenn. 2001).

C. Each Factor Important To The *Buckman* Analysis Is Present Here.

1. The DEA Is Charged With Balancing Delicate And Competing Objectives.

Like the FDA in *Buckman*, the DEA must balance delicate, difficult, and often competing objectives to ensure that opioid analgesics will remain available to the patients who need them while simultaneously providing for strong anti-diversion efforts. *See, e.g.*, 21 U.S.C. § 801. Congress thus enacted the Controlled Substances Act to "control the supply and demand of controlled substances," *Gonzalez v. Raich*, 545 U.S. 1, 19 (2005), which requires a delicate regulatory balance. Although DEA enacts regulations to prevent diversion, it "takes just as seriously its obligation to ensure that there is no interference with the dispensing of controlled substances to the American public in accordance with the sound judgment of their physicians."

2006 DEA Policy Statement, Dispensing Controlled Substances for the Treatment of Pain, 71 FR 52715 (Sept. 6, 2006). To this end, the regulations recognize that "substantial compliance . . . may be deemed sufficient," vesting DEA with discretion in enforcing the regulatory scheme. 21 C.F.R. § 1301.71(b).

To provide the DEA with enhanced flexibility and discretion to balance these competing concerns, Congress enacted the Ensuring Patient Access and Effective Drug Enforcement Act of 2016, Pub. L. No. 114-145 ("Ensuring Patient Access Act"). Among its amendments to the CSA, Congress established that when the DEA initiates enforcement proceedings against a registrant, the registrant may submit a "corrective action plan" which the DEA may consider to "determine whether denial, revocation, or suspension proceedings should be discontinued, or deferred for the purposes of modification, amendment, or clarification to such plan." 21 U.S.C. §§ 824(c)(2)(C); 824(c)(3). [9]

The Ensuring Patient Access Act's legislative history confirms that finding the right balance between making certain that controlled substances would be available without interruption to the suffering patients who need them while simultaneously battling diversion remained Congress's chief concern. The Act's co-sponsors explained the corrective action plan provisions as "provid[ing] the DEA with the clarity to collaborate with the very people responsible for ensuring that [controlled substances] get to the patients who need them without hurting and harming that distribution chain and while clamping down on diversions and abuse."

[9] It makes no difference that this is a recent statute. "When a new law clearly governs pending cases, Article III does not prevent courts from applying it because each court, at every level, must decide according to existing laws." *Patchak v. Zinke*, 138 S. Ct. 897, 909 (2018) (internal quotation marks and citations omitted). "When the intervening statute . . . affects the propriety of prospective relief, application of the new provision is not retroactive." *Landgraf v. USI Film Prods.*, 511 U.S. 244, 273 (1994) (citations omitted).

161 Cong. Rec. H2330 (daily ed. April 21, 2015) (statement of Rep. Blackburn). Representative Pallone stated that the Act "would help drug distributors, pharmacies, and others work with DEA to achieve the difficult balance between keeping controlled substance prescription drugs away from drug abusers, but not from patients who urgently need them." *Id*. at H2332. Whether Congress struck the optimal balance is, of course, a nonjusticiable political question. *E.g.*, *Japan Whaling Ass'n v. Am. Cetacean Soc'y*, 478 U.S. 221, 230 (1986).

2. The DEA Is Charged With Determining Whether A Wholesale Drug Distributor's Registration Is In The Public Interest.

Every wholesale drug distributor that distributes controlled substances must be registered annually. 21 U.S.C. § 822(a)(1). *See also* 21 C.F.R § 1301.11(a). "In determining the public interest, [in making the registration decision, several discrete] factors shall be considered [including] (1) maintenance of effective control against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, and industrial channels[.]" 21 U.S.C. § 823(b). *See also* 21 C.F.R § 1301.11(a). "The Administrator must consider each factor, though he need not make explicit findings as to each one and can give each factor the weight he deems is appropriate." *Akhtar-Zaidi v. DEA*, 841 F.3d 707, 711 (6th Cir. 2016) (internal quotation marks, brackets, and citations omitted).

3. The DEA Has Powerful Tools To Detect and Investigate A Distributor's Potential Noncompliance Or Attempted "Fraud On The DEA."

a. ARCOS data provides the DEA with data and intelligence to detect a distributor's non-compliance or tolerance of diversion.

"The [DEA] closely observes registered distributors to ensure that their operations are 'consistent with the public interest.'" *Masters Pharm., Inc. v. DEA*, 861 F.3d 206, 212 (D.C. Cir. 2017) (brackets and citations omitted). One of the DEA's most powerful detection and

enforcement tools is its ARCOS system. *See* 21 U.S.C. § 827(d)(1); 21 C.F.R. pt. 1304. As this Court has explained, ARCOS "monitors the flow of . . . opioids, from their point of manufacture through commercial distribution channels to point of sale or distribution at the dispensing/retail level so that federal and state governments can identify the diversion of controlled substances into illicit channels of distribution." *In re Nat'l Prescription Opiate Litig.*, 325 F. Supp. 3d 833, 839 (N.D. Ohio 2018) (Polster, J.) (internal quotation marks and citation omitted). *See also* 21 C.F.R. § 1304.33.

b. The DEA's inspection authority gives it powerful tools to detect a distributor's non-compliance or tolerance of diversion.

The Attorney General may inspect "a registrant or applicant for registration[.]" 21 U.S.C. § 822(f). *See also* 21 C.F.R § 1309.41. "[D]istributors . . . shall be inspected as circumstances may require, based in part on the registrant's history of compliance with the requirements of this chapter and maintenance of effective controls and procedures to guard against the diversion of controlled substances." 21 C.F.R. § 1316.13. DEA inspectors (*see* 21 U.S.C. § 880(b)(2)), may conduct administrative inspections "[f]or the purpose of inspecting, copying and verifying the correctness of records, reports, or other documents required to be kept or made under [the CSA] and otherwise facilitating the carrying out of his functions under [the CSA]." *Id*. § 880(b)(1). *See also id*. § 880(b)(3)(A)-(C); 21 C.F.R § 1316.03(a)-(c). The inspector's authority includes "[c]hecking of records and information on distribution of controlled substances . . . (*i.e.*, has the distribution of controlled substances . . . increased markedly within the past year, and if so why)." 21 C.F.R. § 1316.03(e). *See also id*. § 1316.03(f); *id*. § 1316.06. "[T]he Attorney General may [also] subpena witnesses, compel the attendance and testimony of witnesses, and require the production of any records (including books, papers, documents, and other tangible things which constitute or contain evidence) which

the Attorney General finds relevant or material to the investigation." 21 U.S.C. § 876(a). *See also id*. § 876(c).

c. The DEA has discretion to decide whether and when to exercise the full force of its enforcement powers.

The DEA has always had the "discretion, to permit any person against whom criminal and/or civil action is contemplated under the [CSA] an opportunity to present his views and proposals for bringing his alleged violations into compliance with the law [and to] permit him to show cause why prosecution should not be instituted, or to present his views on the contemplated proceeding." 21 C.F.R. § 1316.31. *See also* 21 U.S.C. § 883. The DEA may also simply issue a warning letter, referred to as a Letter of Admonition, to a registrant suspected of conduct inconsistent with the CSA and its implementing regulations. *Improving Predictability and Transparency in DEA and FDA regulation: Hearing before the H. Comm. on Energy & Commerce, Subcomm. on Health*, 113th Congress 6 (2014) (statement of Joseph T. Rannazzisi, DEA).

The DEA has expressed its broad discretion in other ways. For instance, it may determine that a distributor's "[s]ubstantial compliance with [the CSA's 'suspicious order" reporting requirements] . . . may be deemed sufficient by the Administrator after evaluation of the overall security system and needs of the . . . registrant." 21 C.F.R. § 1301.71(b). "[P]erfection is not the standard for assessing [] compliance with [the 'suspicious order' reporting requirements of] 21 C.F.R. [§] 1301.74(b)." *Masters Pharm., Inc.*, 80 Fed. Reg. 55418-01, 55500 (Drug Enf't Admin. Sept. 15, 2015) (citation omitted), *aff'd*, *Masters Pharm., Inc. v. DEA*, 861 F.3d 206 (D.C. Cir. 2017).

The Attorney General may suspend or revoke a distributor's registration for a number of enumerated reasons, including the catch-all that the distributor "has committed such acts as

would render his registration under section 823 . . . inconsistent with the public interest[.]" 21 U.S.C. § 824(a)(4). *See generally* 21 C.F.R. § 1301.36. "Before taking action pursuant to" § 824, "the Attorney General shall serve upon the . . . registrant [a detailed] order to show cause why registration should not be denied, revoked, or suspended." *Id.* § 824(c)(1). *See also id.* § 824(c)(2)(A)-(B); 21 C.F.R. § 1301.37(b)-(c).

However, under the new Ensuring Patient Access Act, the order to show cause must also notify the distributor "of the opportunity to submit a corrective action plan on or before the date of appearance." 21 U.S.C. § 824(c)(2)(C). And "[u]pon review of any corrective action plan submitted by [the] registrant . . . the Attorney General shall determine whether denial, revocation, or suspension proceedings should be discontinued, or deferred for the purposes of modification, amendment, or clarification to such plan." *Id.* § 824(c)(3). But, even while Congress gave the DEA a new statutory layer of discretion, it preserved intact the DEA's strongest enforcement tools. The opportunity to submit a corrective action plan "shall not apply to the issuance of an immediate suspension order[.]" 21 U.S.C. § 824(c)(5). *See id.* § 824(d); 21 C.F.R. § 1301.36(e). *See also* 21 U.S.C. § 824(c)(4), § 824(d).

It has always been unlawful "to refuse or negligently fail to make, keep, or furnish any . . . report [or] notification" or other "information required under" the CSA. 21 U.S.C. § 842(a)(5). Likewise, it has always been unlawful "to furnish false or fraudulent material information in, or omit any material information from, any . . . report . . . required to be made . . . under [the CSA]." 21 U.S.C. § 843(a)(4)(A). *See also id.* §§ 843(d)(1); § 843(b). The penalties for any such violations are severe. *Id.* §§ 842(c)(1)(A); 842(c)(1)(B)(i)-(ii); 842(c)(2)(A); 843(d)(1). Moreover, any such false reporting need not actually succeed in deceiving the DEA

before such penalties may be imposed. 21 U.S.C. § 846. *See also* 18 U.S.C. § 371; 21 U.S.C. § 847.

Most important, the enforcement regime designed by Congress and the DEA works exactly as it is designed to work. *E.g.*, *Southwood Pharms., Inc.; Revocation of Registration*, 72 Fed. Reg. 36487-01, 2007 WL 1886484 (Drug Enf't Admin. July 3, 2007). And these Plaintiffs lack standing to argue otherwise. *E.g.*, *Heckler v. Chaney*, 470 U.S. 821, 831-34 (1985); *see also id*. at 838 ("[W]e essentially leave to Congress, and not to the courts, the decision as to the whether an agency's refusal to institute [enforcement] proceedings should be judicially reviewable."). Equally certain, the DEA, like "[t]he FDA is an expert body, and better placed to set drug policy than . . . state juries in after-the-fact verdicts." *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578, 585 (6th Cir. 2013) (citations omitted).

D. Plaintiffs' Claims Are Preempted.

Thus, as in *Buckman*, the Plaintiffs' allegations that the Small Distributors are (i) liable for not reporting sufficient "suspicious orders" to the DEA, and (ii) because they allegedly perpetrated certain undefined frauds on the DEA, are preempted by conflict because "the federal statutory scheme amply empowers the [DEA] to punish and deter fraud against the Administration, and this authority is used by the Agency to achieve a somewhat delicate balance of statutory objectives." 531 U.S. at 348. Under the DEA's broad statutory and regulatory enforcement scheme, like the FDA's, "flexibility is a critical component of the statutory and regulatory framework under which the [DEA] pursues difficult (and often competing) objectives." *Id.* at 349. The kind of massive litigation presented here certainly "exert[s] an extraneous pull on the scheme established by Congress, and it therefore is pre-empted by that scheme." *Id.* at 353.

VI. As a matter of law, a failure to report to a federal agency cannot be the cause of the Plaintiffs' damages.

The Plaintiffs allege that "[w]ithout reporting by those involved in the supply chain, law enforcement may be delayed in taking action—or may not know to take action at all." TAC ¶ 570. Partial summary judgment should be granted against that theory because it "is either preempted or based on speculation." *Rheinfrank v. Abbott Labs., Inc.*, 119 F. Supp. 3d 749, 767-68 (S.D. Ohio 2015) (collecting authorities), *aff'd*, 680 Fed. App'x 369 (6th Cir. 2017). *See also Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 776 n.12 (5th Cir. 2011) ("Hughes has asserted other causation theories which are untenable. She asserts that had Boston Scientific properly reported all burns (1) the FDA would have taken some regulatory action against the HTA, including but not limited to removing the HTA from the market. . . . [That] theory is entirely speculative." (citation omitted)). Plaintiffs cannot proceed to trial based on rank speculation that DEA would have behaved differently had the Small Distributors reported more or different information to DEA. *See id.*

Moreover, Plaintiffs have no evidence that the Small Distributors' alleged failure to report more suspicious orders than they did was the factual "but-for" cause or legal proximate cause of Plaintiffs' alleged damages. *E.g.*, *Lescs v. William R. Hughes, Inc.*, 168 F.3d 482 (mem.) (text at 1999 WL 12913, at *9) (4th Cir. Jan. 14, 1999) ("Lescs offers no evidence that her alleged injuries were caused by Dow's failure to report the adverse environmental effects of Dursban. She has thus not met her burden on an essential element of her claim and summary judgment is appropriate." (citation omitted)).

CONCLUSION

The Small Distributors' Motion for Partial Summary Judgment is narrow. It demonstrates four essential points. First, Ohio common-law rejects the idea that there is a state-

law duty to not defraud a federal agency or a duty to make federally required reports to a federal agency. Second, it demonstrates that Plaintiffs are trying to pursue private causes of action and private remedies under a federal statute that does not provide them. Third, it demonstrates that "fraud on the agency" and "failure to report" claims are impliedly preempted under ordinary conflicts principles. Fourth, it demonstrates that there cannot be a causal connection between a distributor's "failure to report" more suspicious orders to the DEA than it did and Plaintiffs' alleged damages.

Plaintiffs cannot usurp the enforcement authority that the DEA and the DOJ alone may exercise. Nor may Plaintiffs use litigation as the vehicle to solve problems entrusted to the legislative and executive branches of government. True, "[t]he heroin and opioid epidemic is one of the great public health problems of our time." *U.S. v. Walker*, 2017 WL 2766452, at *5 (S.D. W. Va. June 26, 2017). "Nevertheless, policy reform, coordinated education efforts, and expansion of treatment programs are not within [the Court's] bailiwick." *Id*. at *13.

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CERTIFICATE OF SERVICE

I, William E. Padgett, certify that the foregoing document was served via the Court's ECF system to all counsel of record.

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